

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent Application No. 10/508,978

Confirmation No. 4494

Applicant: Hwu et al.

Filed: November 19, 2004

TC/AU: 1643

Examiner: Bradley Duffy

Docket No.: 230591 (Client Reference No. E-137-2002/0-US-03)

Customer No.: 45733

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.132 OF DR. J. WARREN LEONARD**

1. I, Warren J. Leonard, M.D., am a co-inventor of the subject matter disclosed and claimed in the above-identified patent application.
2. Currently, I am Chief of the Laboratory of Molecular Immunology, Director of the Immunology Center, and Deputy Scientific Director of the National Heart, Lung, and Blood Institute of the National Institutes of Health. I received my Medical Degree from Stanford University in 1977 and have authored over 240 scientific articles during my career.
3. In an open-label, two-arm, phase I trial of human IL-21 for patients with malignant melanoma, patients received a recombinant human IL-21 molecule by intravenous bolus injection. See, Davis et al., *Clin. Cancer Research* 13(12): 3630-3636 (2007); a copy of which is attached hereto. Davis et al. report therein that the absolute number of natural killer (NK) cells decreased in the treated patients, whereas NK cell cytolytic activity in these